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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,048	08/23/2001	C. Frank Bennett	ISPH-0567	1653

7590

06/27/2003

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EXAMINER

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

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DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,048

Applicant(s)

BENNETT ET AL.

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 12-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I and the species "modulation of inflammation" in Paper No. 10, filed 4/25/03 is acknowledged. The traversal is on the ground(s) that all of the claims are drawn to the use of antisense libraries for identification of gene function and that the search of all of the claims would be coextensive and further that the invention of Groups I and II are both drawn to characterize and distinguish cells. This is not found persuasive because the claimed methods are not so related as argued. Groups I and II are not drawn to characterizing cells but Group I is drawn to method of identifying genes involved in a response of a cell to a stimulus while the method of group II is drawn to the identification of one or more genes involved with a phenotype of a cell. The invention of group II does not require the phenotype involve a response to a stimulus and the invention of group 1 requires a response, which requires the application of a stimulus to the cells, for example. The search of Group II would not require a search of cell stimulators, for example. It is noted that both secretion of a of a compound and modulation of expression of a cell adhesion molecule fall within the scope of "modulation of inflammation and will be examined in this Official action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and claims 12-14 are withdrawn from further consideration as being drawn to a non-elected species, there being no

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allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites, "wherein said compound is". There is insufficient antecedent basis for this language and the claims (3 and 4) are left vague and indefinite as a result.

Claims 1, 2, 5, 6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al [US 6,080,580].

The instantly claimed invention is drawn to a method for (1) identifying a gene involved in a response to a stimulus where the method comprises contacting cells with antisense from a library prior to the application of a stimulus, (2) where the response can be secretion of a compound (3) where the compound is a cytokine (4) the response is modulation of inflammation and where the response is inhibited.

Baker et al have disclosed the use of antisense from a library of antisense (see Table 1, Table 2 and Table 3, for example) targeted to TNF- α (a cytokine) which is involved in inflammation response (an inhibition of TNF- α correlates to an inhibition of a cellular inflammatory response (see column 1, for example). It has been disclosed in columns 19-20 a method wherein various antisense oligonucleotides (from a library) were added to different subpopulations of NeoHK cells (see also Table 3, for example).

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The cells were then treated with growth factors. After treatment the expression of TNF- α and the secretion of THF- α was measured. It is clear from Tables 2, 3, 5, 7 and 8 that the response to the stimulus expression of TNF- α mRNA and secretion of TNF- α secretion were variably stimulated and inhibited based on the conditions used and the particular antisense used, for example.

Claims 1, 2, 7, 8, 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al [US 5,514,788].

Bennett et al have disclosed the use of antisense targeted to various cell adhesion molecules, which are involved in inflammation. Inhibition of cell adhesion molecules inhibits inflammatory response of cells, for example (see columns 1-2, for example) Bennett et al have disclosed the inhibition of adhesion proteins such as ICAM VCAM and ELAM with antisense oligonucleotides from antisense libraries defined in Tables 1, 2, 3, and 4, for example. It has been disclosed in Example 1 VCAM, ICAM, and ELAM expression is measured after cells (subpopulations) were treated with antisense to various cell adhesion molecules prior to challenge of the cells to various cytokines. It can be seen in tables 3, 5, 4 and Example 6 the stimulation and inhibition of cell adhesion molecule expression in response to the application of various cytokines under various conditions, for example.

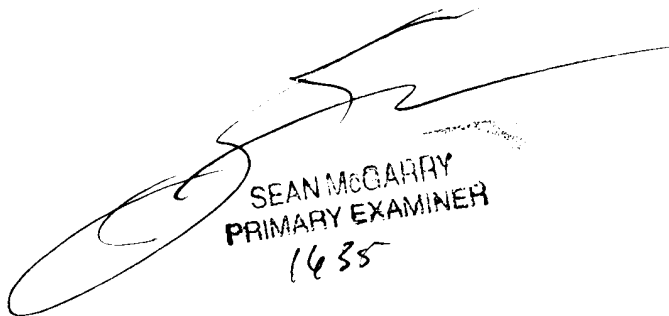
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
June 25, 2003



SEAN MCGARRY
PRIMARY EXAMINER
1635